

## **REMARKS**

### **I. Status of the Application**

Claims 1-31 have been withdrawn, without prejudice. Claims 32-50 are currently pending and stand rejected. By way of this response, claims 32, 35, 38-39, 43, 45-46 and 48 have been amended. Claims 53-71 have been added. Applicant submits that no new matter has been added by way of this amendment.

### **II. Claim Rejections – 35 U.S.C. § 112, ¶ 2**

Claims 39, 43 and 44 have been rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. Applicant submits that the current amendments to claims 32 and 39 overcome this rejection. Claim 32 has been amended to recite “a thickener,” and claim 39 has been amended to recite “C1-C4 alcohol” instead of “lower alcohol” in accordance with proper antecedent basis for these limitations. Thus, Applicant respectfully requests that this rejection be withdrawn.

### **III. Claim Rejections – Obviousness-Type Double Patenting**

Claims 32, 39-42, 45, 46 and 50 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 13, 14, 22-30, 35-37, 39, 52, 58, 60 and 64 of co-pending Application No. 10/825,540 in view of Reed et al. (US 6,299,900). Claims 32, 39-42, 45-46 and 50 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 13, 14, 22-30, 35-37, 39, 40 and 44-47 of co-pending Application No. 10/828,678 in view of Reed et al. Lastly, claims 32, 40-42, 45 and 47 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33, 38, 46, 58, 67-69, 70 and 73 of co-pending Application No. 10/828,678 in view of Reed et al. Applicant

respectfully traverses these rejections and respectfully requests that the rejections be withdrawn in light of the arguments set forth below and the present amendments to the claims.

In the Office Action, the Examiner alleges that Application No. 10/825,540 and Application No. 10/828,678 each teach a method of treating hypogonadism in a male subject comprising applying a gel containing testosterone to skin of a male subject. The Examiner further alleges that Reed et al. teaches a percutaneous or transdermal delivery system comprising at least one physiologically active agent such as testosterone, at least one volatile liquid as ethanol and a penetration enhancer such as isopropyl myristate. The Examiner stated that one of ordinary skill in the art would have found it obvious to combine either the '540 application or '678 application and Reed et al. to yield the specific method of improving the efficacy of a pharmaceutical useful for treating erectile dysfunction because Reed et al. teaches that a lack of efficacy of systemic drugs provides an effective method of achieving improved bioavailability for physiologically active substances.

As amended, claim 32 requires a “method for improving the efficacy of a pharmaceutical other than testosterone, which pharmaceutical is useful for treating erectile dysfunction in a male subject...” None of the references cited by the Examiner provide any teaching to any other pharmaceutical agent used in combination with testosterone. Claim 32 requires the use of another pharmaceutical useful for treating erectile dysfunction in addition to testosterone. Reed et al. does not teach the use of a combination of another pharmaceutical with testosterone. Reed et al. teaches “a non-occlusive, percutaneous or transdermal drug delivery system which comprises: (i) an effective amount of at least one physiologically active agent or prodrug thereof; (ii) at least one non-volatile dermal penetration enhancer; and (iii) at least one volatile liquid...” '900 patent, Abstract. In other words, Reed et al. teaches how to improve transdermal delivery

for a given pharmaceutical. Reed et al. does not teach how to improve the efficacy of more than one pharmaceutical, other than testosterone, useful for treating erectile dysfunction by combining it with percutaneously delivered testosterone, as required by Applicant's pending claims.

In addition, it was clearly not obvious to combine testosterone with another pharmaceutical which is useful for treating erectile dysfunction because Applicant achieved surprising and improved results when testosterone was combined with such a pharmaceutical. See specification as originally filed, pages 47-54, wherein the surprising effects of percutaneously delivered testosterone on the effectiveness of a pharmaceutical for treating erectile dysfunction is reported.

In view of the above, Applicant respectfully requests the reconsideration and withdrawal of the obviousness-type double patenting rejection of the above-identified claims.

#### **IV. Claim Rejections – 35 U.S.C. § 103(a)**

Claims 32, 37-45, 47 and 50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Reed et al. in view of Dittgen et al. (US 6,238,284), in further view of Kim et al. (US 5,482,970). Claims 33 and 48 stand rejected under § 103(a) as being unpatentable over Reed et al. in view of Dittgen et al. (US 6,238,284), in further view of Kim et al. as applied to claims 32, 37-45, 47 and 50, in further view of Wang et al. (Journal of Clinical Endocrinology and Metabolism, August 1998, vol. 83(8), pp. 2749-2757). Lastly, claims 34 and 36 stand rejected under § 103(a) as being unpatentable over Reed et al. in view of Dittgen et al., in further view of Kim et al. as applied to claims 32, 37-45, 47 and 50, in further view of Doherty Jr. et al. (US 6,037,346). Applicant respectfully traverses these rejections and respectfully requests that they be withdrawn in light of the arguments set forth below and the present amendments to the claims.

As explained above, Reed et al. does not disclose each and every element of amended claim 32. Moreover, no combination of Reed et al., Dittgen et al., Kim et al., Wang, and Doherty Jr. et al., discloses all of the elements of the pending claims as amended. Therefore, the claims as amended are patentable over Reed et al., Dittgen et al., Kim et al., Wang, and Doherty Jr. et al. Dittgen et al. teaches a transdermal therapeutic system for application to the skin consisting of at least one active substance in the form of a solid dispersion in combination with at least one destructuring agent and/or at least one structuring agent in a common matrix. '284 patent, Abstract. Next, Kim et al. relates to a composition and a method of controlling membrane penetration comprising an antiandrogenic tricyclic compound of the disclosed formula 1. '970 patent, Col. 1, ll. 7-10. Wang teaches comparative pharmacokinetics of specific doses of dihydrotestosterone (DHT). Finally, Doherty Jr. et al. teaches local administration of a phosphodiesterase inhibitor within the context of an effective dosing regime. '346 patent, Abstract. There is no teaching or suggestion in Doherty Jr. et al. to simultaneously administer a phosphodiesterase inhibitor and testosterone. Indeed, none of the prior art cited by the Examiner teaches the use of testosterone in combination with an additional pharmaceutical which is useful for treating erectile dysfunction for improving the efficacy of the pharmaceutical. As stated above, Applicant achieved surprising and unexpected results when administering testosterone and such a pharmaceutical, such as a phosphodiesterase inhibitor, to a male subject. See specification as originally filed, pages 47-54. Accordingly, it was not obvious to one of ordinary skill in the art to concurrently administer the two pharmaceuticals.

As amended claim 32 is patentable over Reed et al., Dittgen et al., Kim et al., Wang, and Doherty Jr. et al., claims 33-50 are also patentable as they depend on claim 32.

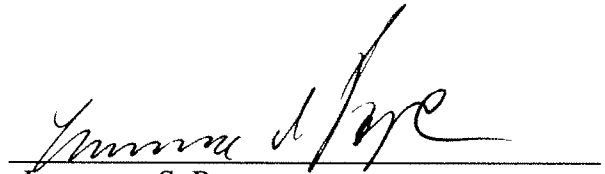
For the foregoing reasons, Applicant submits that no *prima facie* case of obviousness has been established and respectfully requests withdrawal of the outstanding prior art rejections.

### CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the pending claims are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,



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